

**REMARKS**

In this Amendment, claims 20, 30 and 32 are amended, and claim 25 is canceled. Thus, after entry of this Amendment, claims 20-24, 26-30, 32 and 33 will be pending in the application.

Claim 20 has been amended to recite that the “protein sequences are predicted from whole genomic sequences or are predicted from partial genomic sequences comprising at least one chromosome.” This amendment is supported by the specification at page 24, lines 3-5, describing the claimed method with partial genomic sequences of *P. falciparum* and *L. major*. Further, at page 26, the specification shows predicting protein sequences and identifying outlier proteins from one chromosome of *L. major*, and shows that partial and whole genomic sequences of other pathogens were used to identify outliers.

Claim 20 was also amended to recite “selecting an outlier protein for further testing as an anti-infective.” This amendment is supported by the specification at page 1, lines 12-14, for example, stating that outlier proteins constitute a set of candidates for further testing in development of anti-infectives.

Claim 25 has been canceled as this claim does not further limit independent claim 20.

Claims 30 and 32 have been amended to more explicitly set forth an additional step of the claimed method.

**Response to Claim Rejections Under 35 U.S.C. § 101**

At page 2 of the Office Action, claims 20-28 are rejected under 35 USC § 101, because in the Examiner’s opinion, the claims are directed toward non-statutory subject matter. The

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Examiner contends that the claims encompass a method performed on a computer that lacks any physical result performed outside of a computer, and that this renders these claims non-statutory.

In response to Applicants' argument that the courts have recognized computer programs and mathematical algorithms and/or formulas as patentable subject matter when applied in a useful way, the Examiner agrees, but contends that the method steps of claims 20-28 do not recite how the algorithms are applied.

Further, in response to Applicants' discussion of *Arrhythmia Research Technology, Inc. v. Corazonix, Corp.*, 22 USPQ2d 1033 (Fed. Cir. 1992), showing that algorithms applied in a useful way are patentable even where the method is performed entirely on a computer, the Examiner simply responds that every patent application is examined on its own facts.

The Examiner believes that claims 20-28 do not provide a practical application, and that any such practical application must be explicitly recited in the claims. Further, the Examiner believes that the phrase "identifying a candidate protein useful as an anti-infective" in the preamble of claim 20 is insufficient to render the claim statutory since this phrase is not recited in the method steps.

Applicants have amended independent claim 20 to recite, after step (c), "selecting an outlier protein for further testing as an anti-infective." This amendment even more explicitly places the practical application in the method steps of the independent claim, and addresses the Examiner's comments regarding noise filtering and noise analysis on page 4 of the Office Action (which are interpreted to mean that one must "select" an outlier protein as opposed to just "identify" an outlier protein).

In view of the above, withdrawal of this rejection is requested.

If the Examiner still believes that the claims are directed toward non-statutory subject matter, and Applicants are left to appeal, then the following comments are made of record.

First, the Office Action conflates the use of the algorithm with the use of the outlier protein identified by the method. The claims are statutory because they apply the algorithm to protein sequences; that is, the algorithm is not claimed in the abstract but only in connection with the useful purpose of identifying anti-infective proteins from a pathogenic organism. As shown in the specification, these proteins have potential diagnostic and therapeutic value. However, the exact manner in which the anti-infective is ultimately used, does not change the manner in which the algorithm was *previously* used to identify the protein as an anti-infective. Thus, in the present claims the algorithm is applied in a useful way.

Second, the law does not change from patent application to patent application. The Examiner's rebuttal of legal arguments, by merely stating that each application is examined on its own facts, is improper. *Arrhythmia Research Technology*, as discussed in the Amendment filed September 14, 2004,<sup>1</sup> shows that algorithms applied in a useful way are patentable even

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<sup>1</sup> As stated in the Amendment filed September 14, 2004, in *Arrhythmia Research Technology, Inc. v. Corazonix, Corp.*, 22 USPQ2d 1033 (Fed. Cir. 1992), all steps of the claim were performed on a computer. In finding that claim 1 was directed toward statutory subject matter, the Federal Circuit found that the input signals "are not abstractions; they are related to the patient's heart function," and further, that claim 1 does not seek to patent a mathematical formula in the abstraction, but merely to patent its use in connection with the claimed process of analyzing electrocardiac signals. *Id* at 1038. In the present case, the protein sequences are also not abstractions, but represent physical objects (protein molecules), and claim 20 does not seek to patent the algorithm in the abstraction but only in connection with the claimed process of analyzing protein sequences of a pathogenic organism to identify an anti-infective.

where the method is performed entirely on a computer. Indeed, this is a rule of law and is not limited only to that particular patent application at issue in the decision.

Further, the Office Action, at the top of page 6, states that *Arrhythmia* is not controlling because the decision relates to a particular patent application which must be examined on its own facts, but the *same* Office Action nevertheless cites to *Arrhythmia* at page 3.

Thus, it is again asserted that *Arrhythmia Research Technology, Inc. v. Corazonix, Corp.*, 22 USPQ2d 1033 (Fed. Cir. 1992) supports that the present claims are directed to statutory subject matter, and that these arguments have not been addressed by the office.

#### **Claim rejections under 35 U.S.C. § 112, first paragraph**

(1) At page 6 of the Office Action, the Examiner rejects claims 20-30 and 32-33 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

Specifically, the Examiner believes that the omission of the step “comparing said outlier proteins to known proteins to identify a unique outlier protein” in the Amendment filed September 14, 2004 introduces new matter.

The Examiner is directed to the Examples in the specification.

In Example 5, seven outlier proteins were identified in *M. tuberculosis* (steps (a)-(c) of claim 20), three outlier proteins were selected (corresponding to step (d) of amended claim 20), and then validated by reviewing relevant literature (corresponding to the final step of the claim). Thus, Example 5 does not show a method that includes a step of identifying a “unique” outlier protein, as the outlier proteins were discussed in the literature. Example 5 shows all steps recited in the amended claims.

In Example 6, eight outlier proteins were identified in *H. pylori* (steps (a)-(c) of claim 20), one outlier protein was selected (corresponding to step (d) of amended claim 20), and validated by reviewing relevant literature (corresponding to the final step of the claim). Thus, Example 6 does not show a method that includes a step of identifying a “unique” outlier protein, as the outlier protein was discussed in the literature. Example 6 shows all steps recited in the amended claims.

In Example 7, five outlier proteins were identified in *P. falciparum* (steps (a)-(c) of claim 20), one outlier protein was selected (corresponding to step (d) of amended claim 20), and then validated by reviewing relevant literature (corresponding to the final step of the claim). Thus, Example 7 does not show a method that includes a step of identifying a “unique” outlier protein, as the protein was discussed in the literature. Example 7 shows all steps recited in the amended claims.

Thus, the omission of the step “comparing said outlier proteins to known proteins to identify a unique outlier protein” in the Amendment filed September 14, 2004 did not introduce new matter.

Withdrawal of this rejection is respectfully requested.

(2) At page 8 of the Office Action, claims 20-30 and 32-33 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement.

Specifically, the Examiner contends that computationally analyzing “all” protein sequences of a pathogenic organism is not enabled by the specification. The Examiner believes that the determination of “all” proteins of any organism is but mere speculation, and cannot be accurately determined even with simple organisms.

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The term "all" has been deleted from claim 20, and replaced with "wherein said protein sequences are predicted from whole genomic sequences or are predicted from partial genomic sequences comprising at least one chromosome." The Examiner is directed to the Examples in the specification providing numerous working examples of predicting outlier sequences by the method as defined by the amended claims.

In view of the above, Applicants request withdrawal of the present rejection.

### Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
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Date: February 18, 2005